REMARKS

The Final Office Action of September 17, 2004, has been received and reviewed. Claims 15, 18, 21-25, 32, 33, 35-40 and 50-57 are pending in the application and all pending claims stand rejected. Applicant proposes to amend claims 18, 21-25, 32-33, 38, 50 and 53-55, and cancel claims 15, 35-37, 39-40, 51-52 and 56-57 as set forth herein. No new matter has been added. Reconsideration is requested.

Documents

The Final Office Action of September 17, 2004, noted that a certified copy of EP 98202456.5 and the new oath/declaration had not yet been received. These documents were submitted to the Office on September 22, 2004. An English translation of the Abstract of EP 0750043A1 was also requested. Submitted herewith in a supplemental Information Disclosure Statement is U.S. Patent 5,733,765 which is in the same family as EP 0750043A1. Thus, an English translation should no longer be necessary.

Rejections under 35 U.S.C. § 112, first paragraph

Written Description

Claims 52-55

Claims 52-55 stand rejected under 35 U.S.C. § 112, first paragraph, as assertedly failing to comply with the written description requirement. Claim 52 has been canceled rendering the rejection thereof moot. At least partially in view of the proposed amendments to claims 53-55, applicant respectfully traverses the remaining rejections.

Specifically, it was thought that the applicant has not shown the genus of the *S. suis* gene mutants that are deficient in capsular expression. (*See*, Final Office Action, page 3). Although applicant does not agree with any of the written description rejections, to expedite prosecution, applicant proposes to amend claims 53-55 to depend from amended claim 18.

As amended, claim 18 is directed towards a composition comprising a *S. suis* bacterium deficient in capsular expression, wherein the *Streptococcus suis* mutant comprises a mutation in a sequence selected from the group consisting of SEQ ID NO: 9, SEQ ID NO: 29, SEQ ID NO: 37 and SEQ ID NO: 43. Written description exists for the mutants recited in amended claim 18

as discussed herein. Thus, one of ordinary skill in the art should conclude that the inventor is in possession of amended claims 53-55 that depend from amended claim 18.

Reconsideration and withdrawal of the written description rejections of claims 53-55 are requested.

Claims 15, 18, 21-25, 32, 33, 35-40, 50, 51, 56 and 57

Claims 15, 18, 21-25, 32, 33, 35-40, 50, 51, 56 and 57 stand rejected under 35 U.S.C. § 112, first paragraph, as assertedly failing to comply with the written description requirement. Claims 15, 35-37, 39-40, 51 and 56-57 have been canceled rendering the rejections thereof moot. At least partially in view of the proposed amendments, applicant respectfully traverses the remaining rejections as set forth herein.

Claim 18 has been amended to be directed towards a composition comprising a *Streptococcus suis* bacterium deficient in capsular expression, wherein the *Streptococcus suis* mutant comprises a mutation in a sequence selected from the group consisting of SEQ ID NO: 9, SEQ ID NO: 29, SEQ ID NO: 37 and SEQ ID NO: 43, and a pharmaceutically acceptable carrier or adjuvant.

One of ordinary skill in the art would conclude that the inventors were in possession of amended claim 18 since the as-filed specification describes how to produce a *Streptococcus* mutant deficient in capsular expression by mutating a sequence. (*See*, Specification, as-filed, page 14, lines 25-35). The as-filed specification further describes that SEQ ID NO: 9 is the nucleotide sequence of CPS2, SEQ ID NO: 29 is the nucleotide sequence of CPS1, SEQ ID NO: 37 is the nucleotide sequence of CPS9, and SEQ ID NO: 43 is the nucleotide sequence of CPS7. For instance, written description exists in the as-filed specification as follows: CPS2, (*See*, *Id.* at page 10, lines 10-27; describing an isolated nucleic acid of FIG. 3, *i.e.*, SEQ ID NO: 9), CPS1 (*See*, *Id.* at page 10, lines 29-32; describing an isolated nucleic acid of FIG. 4, *i.e.*, SEQ ID NO: 29), CPS9 (*See*, *Id.* at page 10, lines 33-36; describing an isolated nucleic acid of FIG. 5, *i.e.*, SEQ ID NO: 37), and CPS7 (*See*, *Id.* at FIG. 6 and page 55, lines 22-33, *i.e.*, SEQ ID NO: 43). The as-filed specification further describes a vaccine (*i.e.*, which is a composition) comprising a *Streptococcus* mutant and a "pharmaceutically acceptable carrier adjuvant." (*See*, *Id.* at page 18,

lines 1-7). Thus, one of ordinary skill in the art would conclude that the inventors were in possession of the composition of amended claim 18.

Claims 21-25, 32, 33, 38 and 50 should also comply with the written description requirement as depending from amended claim 18.

Reconsideration and withdrawal of the written description rejections of claims 18, 21-25, 32, 33, 38 and 50 are requested.

Enablement

Claims 15, 18, 21-25, 32, 33, 35-40 and 50-57 stand rejected under 35 U.S.C. § 112, first paragraph, as assertedly failing to comply with the enablement requirement. Claims 15, 35-37, 39-40, 51-52 and 56-57 have been canceled rendering the rejections thereof moot. Applicant respectfully traverses the remaining rejections as set forth herein.

Specifically, it was asserted that the specification does not enable vaccines, and that the specification does not teach a working example or a single point of data regarding a specific immune response. (*See*, Final Office Action at page 4). In formulating the enablement rejection, the Final Office Action indicated that "enablement must be established at the time of filing not at some later date" and that "no evidence of antibody production is taught by this specification at all." (*Id.* at pages 5-6). Although applicant does not agree than any of the claims lack compliance with the enablement requirement, to expedite prosecution, amended claim 18 is directed towards a composition comprising a *Streptococcus suis* mutant deficient in capsular expression, wherein the *Streptococcus suis* mutant comprises a mutation in a sequence selected from the group consisting of SEQ ID NO: 9, SEQ ID NO: 29, SEQ ID NO: 37 and SEQ ID NO: 43; and a pharmaceutically acceptable carrier or adjuvant.

The MPEP states "as long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. § 112 is satisfied." (M.P.E.P. § 2164.01(b), *citing In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970)). Since the as-filed specification discloses how to make and use a *Streptococcus suis* mutant, and how to combine the *Streptococcus suis* mutant with a pharmaceutically acceptable carrier or adjuvant, one of ordinary skill in the art would be able to make and use the composition of amended claim 18.

For instance, the as-filed specification teaches how to construct mutants of *Streptococcus suis* by knocking out or disturbing 10cpsB and 10cpsEF genes. (*See*, Specification as-filed, page 25, lines 5-21; *see also*, *Id.* at page 38, lines 9-34). The as-filed specification further discloses nucleic acid sequences of CPS2 (*See*, *Id.* at page 10, lines 10-27; describing an isolated nucleic acid of FIG. 3, *i.e.*, SEQ ID NO: 9), CPS1 (*See*, *Id.* at page 10, lines 29-32; describing an isolated nucleic acid of FIG. 4, *i.e.*, SEQ ID NO: 29), CPS9 (*See*, *Id.* at page 10, lines 33-36; describing an isolated nucleic acid of FIG. 5, *i.e.*, SEQ ID NO: 37), and CPS7 (*See*, *Id.* at FIG. 6 and page 55, lines 22-33, *i.e.*, SEQ ID NO: 43). Thus, one of ordinary skill in the art would be able to make and use the composition including the *Streptococcus suis* mutant of amended claim 18 without undue experimentation.

The Final Office Action further asserted that "the art at the time of filing indicates that the capability to generate an immune response is not correlated with protection from disease" and "there is no evidence of record for protection using the *S. suis* mutant to express a non-streptococcus virulence protein or a Streptococcus virulence factor or antigenic determinant." (Final Office Action at pages 5 and 7). Although applicant does not agree with the enablement rejection, to expedite prosecution, claim 18 has been to be directed towards a composition rather than a vaccine. Thus, since amended claim 18 is no longer directed towards a vaccine, the specification does not have to disclose 100% protection to be enabled as asserted by the Final Office Action.

As is known in the art, antibodies directed against capsule antigens are serotype-specific and confer protection against only one serotype. (*See*, Specification as-filed at page 8, lines 2-17). However, the composition of amended claim 18 is capable of eliciting an immune response against heterologous strains. (*See*, *Id.* at page 15, lines 9-29). Further, the as-filed specification indicates that *Streptococcus suis* capsular mutants are less virulent in germ-free pigs, thus, providing protection. (*See*, *Id.* at page 39, line 17 through page 40, line 15). The applicant is also allowed to provide other evidence of enablement.

As stated in the MPEP, "applicant should be encouraged to provide **any** evidence to demonstrate that the disclosure enables the claimed invention" and that "once that evidence is submitted, it **must** be weighed with all other evidence." (M.P.E.P. § 2164.05) (emphasis added). The MPEP also states "applicant must demonstrate by argument and/or evidence that the

disclosure, as filed, would have enabled the claimed invention." (*Id.*) Thus, the applicant is allowed to show enablement by reference to the scientific paper of Wisselink et al., Vet. Mic. (2002) 84: 155-168.

Since one of ordinary skill in the art would be able to make and use the composition of amended claim 18, amended claim 18 should be enabled.

Claims 21-25, 32, 33, 38 and 53-55 are enabled as depending from enabled, amended claim 18.

Reconsideration and withdrawal of the enablement rejections of claims 18, 21-25, 32, 33, 38 and 53-55 are requested.

Rejections under 35 U.S.C. § 102(b)

Claims 15, 18, 21, 22, 23, 32, 33, 35, 36, 37, 38, 39, 52, 54 and 56 stand rejected under 35 U.S.C. § 102(b) as assertedly being anticipated by Charland et al. Claims 15, 35-37, 39, 52 and 56 have been canceled rendering the rejections thereof moot. Applicant respectfully traverses the rejection as hereinafter set forth.

Amended claim 18 cannot be anticipated since Charland et al. does not expressly or inherently disclose each and every element of amended claim 18. For instance, Charland et al. does not disclose a *Streptococcus suis* mutant comprising a mutation in a sequence selected from the group consisting of SEQ ID NO: 9, SEQ ID NO: 29, SEQ ID NO: 37 and SEQ ID NO: 43 as recited in amended claim 18. In fact, it is not known what mutation(s) caused the capsule deficiency of Charland et al.

Since claims 21, 22, 23, 32, 33, 38, 54 and 56 depend from novel independent claim 18, claims 21, 22, 23, 32, 33, 38, 54 and 56 also include the elements of novel independent claim 18. Thus, as Charland et al. cannot anticipate amended claim 18, Charland et al. also cannot anticipate claims 21, 22, 23, 32, 33, 38, 54 and 56 which include the elements of amended claim 18.

Reconsideration and withdrawal of the anticipation rejections of claims 18, 21, 22, 23, 32, 33, 38, 54 and 56 are requested.

Provisional Objections under 37 C.F.R. § 1.75

The Final Office Action indicated that should claims 21-23 and 39 be found allowable, that claims 35-37 and 39 will be objected to under 37 C.F.R. § 1.75 as assertedly being substantial duplicates thereof. Claims 35-37 and 39 have been canceled rendering the provisional objections moot.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 15, 18, 21-25, 32, 33, 35-40 and 50-57 stand rejected under 35 U.S.C. § 112, second paragraph, as assertedly being indefinite. Claims 15, 35-37, 39-40, 51-52 and 56-57 have been canceled rendering the rejections thereof moot. At least partially in view of the proposed amendments, reconsideration and withdrawal of the remaining indefiniteness rejections are requested.

Specifically, it was thought that the term "stable" was not defined in the specification, thus, rendering the claims indefinite. (*See*, Final Office Action at pages 8-9). Although applicant does not agree that any of the claims are indefinite, to expedite prosecution, the term "stable" has been removed from the pending claims.

It was also thought that certain claims (*i.e.*, claims 35, 36, 37 and 39) were identical to other pending claims. Although applicant does not agree with the asserted rejections, claims 35-37 and 39 have been canceled.

Reconsideration and withdrawal of indefiniteness rejections of claims 18, 21-25, 32, 33, 38, 50 and 53-55 are requested.

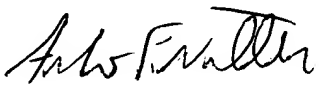
ENTRY OF AMENDMENTS

The proposed amendments to claims 18, 21-25, 32-33, 38, 50 and 53-55 should be entered because they are supported by the as-filed specification and drawings, and do not add any new matter. Further, the amendments should not raise new issues or require a further search. The proposed amendments should also be entered since they comply with requirements as to form (*i.e.*, be removing 35 U.S.C. § 112 issues). Finally, if the Examiner determines that the amendments do not place the application in condition for allowance, entry is respectfully requested since they certainly remove issues for appeal.

CONCLUSION

In view of the foregoing amendments and remarks, the applicant submits that the claims define patentable subject matter and a notice of allowance is requested. Should questions remain after consideration of the foregoing, the Office is kindly requested to contact the applicant's attorney at the address or telephone number given herein.

Respectfully submitted,



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